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TRANSMITTAL FORM

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Total Number of Pages in This Submission: 26

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Filing Date	March 4, 2002
First Named Inventor	Robert Wyckoff
Art Unit	3743
Examiner Name	Andrea M. Ragonese
Attorney Docket Number	1521.2

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☑ After Final COPY
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
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- ☐ Drawing(s)
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  PTO/SB/30 RCE Transmittal
  Itemized Return Receipt Postcard

Remarks

The fees associated with the RCE and the Petition for Extension of Time are to be charged to our Deposit Account as noted on the PTO/SB/30 RCE Transmittal form.

This RCE and supporting documents is being submitted via Express Mail procedure rather than First-Class Mail.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Summa, Allan& Additon, P.A.		
Signature	Jesse B. Ashe		
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Date	December 2, 2005	Reg. No.	44,513

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below: EV 612632258 US

Signature	Patti Summers		
Typed or printed name	Patti Summers	Date	December 2, 2005

COPY

Attorney Docket No. 1521.2 **Patent**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Wyckoff
Serial No. 10/090,268
Filed: March 4, 2002
For: SLEEP APNEA DEVICE AND METHOD THEREOF

Art Unit: 3743
Confirmation No. 4134
Examiner: A. Ragonese

October 3, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

In response to the Official Action dated June 3, 2005, please amend the above-identified application as follows:

Amendments to the Specification begin on page 2.

Amendments to the Claims are reflected in the listing of claims which begins on page 3.

Amendments to the Drawings begin on page 9 of this paper and include replacement sheets.

Remarks begin on page 10.

Appendix including seven replacement drawing sheets is attached following page 23.

AMENDMENTS TO THE SPECIFICATION

Please amend paragraph 2, page 13, as follows:

The preferred positioning of seal 38 proximate to peripheral edge 29 of device 10 enables formation of a substantially airtight zone 42 between inner surface 22 of device 10 and the neck of a user. Preferably, valve 44 and valve cover 44a is provided on support member 20, wherein valve 44 is configured to permit one-way passage of air from airtight zone 42, thus enabling the creation of a negative pressure or vacuum between inner surface 22 of device 10 and the neck of a user, that is, within airtight zone 42.

AMENDMENTS TO THE CLAIMS

1. (Currently amended) An air pathway clearance device for wear on the neck of a user, comprising:

a support member, said support member having an inner surface, an outer surface and a peripheral edge;

securing means, said securing means carried by said support member and said securing means enabling retention of said support member on the neck of the user;

retention means, said retention means enabling retention of said securing means relative to said support member;

a seal, said seal secured to ~~sealing means, said sealing means carried by said support member proximate to~~ and extending substantially coextensive with said peripheral edge of said inner surface of said support member, said seal~~ing means~~ enabling substantially airtight positioning of said support member against the neck of the user, said seal~~ing means generally~~ protruding laterally beyond ~~from~~ said inner surface of said support member such that portions of said inner surface of said support member are spaced apart from the neck of the user, ~~and said sealing means defining an air compartment between said inner surface of said support member and the neck of a user~~;

an air compartment that is defined by an area bound by said inner surface of said support member, said seal, and the neck of the user; and

at least one valve, said valve carried by said support member, wherein said valve enables the exit of air from said air compartment between said inner surface of said support member and the neck of the [a] user during expansion of the neck during exhalation;

wherein a generally negative pressure is created in said air compartment during subsequent inhalation such that the negative pressure on the exterior surface of the neck holds open air pathways of the user.

2. (Original) The air pathway clearance device of Claim 1, wherein said support member is generally arcuately shaped and is formed from substantially rigid material.

3. (Original) The air pathway clearance device of Claim 2, wherein said arcuate shape of said support member is adjustable.

4. (Original) The air pathway clearance device of Claim 1, wherein said support member is formed from substantially flexible material.

5. (Currently amended) The air pathway clearance device of Claim 1, wherein said securing means is at least one strap and said retention means is a hook and loop fastener.

6. (Original) The air pathway clearance device of Claim 1, wherein said securing means is at least one strap and said retention means is at least one buckle.

7. (Original) The air pathway clearance device of Claim 1, wherein said securing means is at least one strap and said retention means is at least one snap.

8. (Currently amended) The air pathway clearance device of Claim 1, wherein said securing means is at least one strap and said retention means is at least one clasp.

9. (Original) The air pathway clearance device of Claim 1, wherein said securing means is at least one strap and said retention means is at least one magnet.

10. (Original) The air pathway clearance device of Claim 1, further comprising a cushioning material carried by said support member.

11. (Original) The air pathway clearance device of Claim 10, wherein said cushioning material substantially surrounds said peripheral edge of said support member.

12. (Currently amended) The air pathway clearance device of Claim 1, wherein said seal~~ing means~~ is a rubber gasket.

13. (Original) The air pathway clearance device of Claim 1, further comprising a means for measuring performance.

14. (Original) The air pathway clearance device of Claim 13, wherein said means for measuring performance is a valve.

15. (Original) The air pathway clearance device of Claim 13, wherein said means for measuring performance is electronic data collection instrumentation.

16. (Original) The air pathway clearance device of Claim 1, wherein said support member is formed from a plurality of linked segments.

17. (Currently amended) A sleep apnea device for use on the neck of a user, comprising:

a neck cuff having a generally arcuate shape, a concave surface and a peripheral edge;

at least one strap carried by said neck cuff, said at least one strap having at least one strap fastener for securing the position of said neck cuff on the neck of the user;

a gasket, said gasket secured to and extending substantially coextensive with said peripheral edge of ~~carried proximate to~~ said concave surface of said neck cuff, said gasket protruding beyond said concave surface of said neck cuff such that portions of said concave surface of said neck cuff are spaced apart from the neck of the user, and said gasket defining a sealed region between said concave surface of said neck cuff and the neck of the [a] user;

at least one vacuum regulator, said vacuum regulator carried by said neck cuff, wherein said vacuum regulator permits a unidirectional flow of air from said sealed region;

wherein the unidirectional flow of air from said sealed region creates a generally negative pressure in said sealed region such that the negative pressure on the neck holds open air pathways of the user.

18. (Original) The sleep apnea device of Claim 17, further comprising a generally resilient border substantially covering said peripheral edge of said neck cuff.

19. (Original) The sleep apnea device of Claim 18, further comprising a data collection port.

20. (Original) The sleep apnea device of Claim 17, further comprising a pressure generating device, said pressure generating device assisting the unidirectional flow of air through said at least one vacuum regulator.

21. (Withdrawn) The method of treating sleep apnea comprising the steps of:

a. obtaining a sleep apnea device having a support member with an inner surface, at least one strap carried by said support member, at least one gasket carried proximate to said inner surface of said support member, and at least one valve carried by said support member;

b. placing said sleep apnea device on the neck of a user with said inner surface of said support member proximate to the outer surface of the neck of a user;

c. securing said at least one strap around the neck of a user;

d. forming a generally airtight seal between said gasket and the neck of a user, thereby defining a substantially airtight zone;

e. creating a negative pressure within said substantially airtight zone;

f. utilizing a vacuum resulting from said negative pressure to maintain open air passages for the user.

22. (Withdrawn) The method of treating sleep apnea of Claim 21, wherein said negative pressure is created by allowing air to escape from said substantially airtight zone through said valve, in self-regulated response to respiratory movement of the soft tissues of the neck of the user.

23. (Withdrawn) The method of treating sleep apnea of Claim 21, wherein said placement of said support member on the neck of a user is along the mandibular area and on the clavicular area.

24. (Withdrawn) The method of treating sleep apnea of Claim 23, wherein said support member extends over the frontal neck of the user without exerting pressure on the carotid body.

DRAWING AMENDMENTS

Please substitute the enclosed replacement sheets depicting the proposed replacement Figures 1, 2, 3, 4, 5A, 5B, and 5C.

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REMARKS

As an initial matter, Applicant notes that it has retained new patent counsel in an effort to advance the progress of this application. Further, Applicant appreciates the thorough examination by the Examiner. Enclosed please find an executed PTO/SB/82 Revocation of Power of Attorney With New Power of Attorney and Change of Correspondence Address form.

Replacement Drawing Sheets Provided

The Examiner notes that the drawings received on March 2, 2005 are not accepted. Specifically, the Examiner states that in Figures 5A and 5C, an element on the left side of the drawing does not include a corresponding reference character. With respect to Figures 5A and 5B, the Examiner states that elements 102a, 102b do not have corresponding "snap" elements and requests that the subject elements be shown in the same drawings. Regarding Figures 5B and 5C, the Examiner states that elements 104a, 104b do not have corresponding "magnetic" elements and request that the subject elements be shown in the same drawings.

Applicant submits herein seven replacement drawing sheets in compliance with 37 C.F.R. 1.121(d). In particular, Applicant proposes to substitute drawing sheets 1, 2, 3, 4, 5A, 5B, and 5C with replacement drawing sheets 1, 2, 3, 4, 5A, 5B, and 5C. The proposed replacement drawing sheets now reflect the valve cover 44a as previously unnumbered, the snap and corresponding snap fastener elements 102a, 102b, and the magnet and magnet fastener elements 104a, 104b. The proposed drawings sheets now include formal numbering and more clearly depict the present invention. Applicant submits that the replacement sheets now properly depict the invention in accordance with the Examiner's requests and 37 C.F.R §1.121(d).

Amended Specification

Applicant has amended paragraph 2, page 13, to recite the valve cover as previously depicted in Figures 1, 5A, 5B, and 5C, and now labeled element number 44a.

The Examiner's Rejections

The Examiner rejects claims 1-5 and 10-11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4657003 to Wirtz.

The Examiner also rejects claims 6-9 and 12-20 under 35 U.S.C. §103(a) as being unpatentable over Wirtz in view of—either alone or in combination with—U.S. Patent No. 4886052 to Calabrese, U.S. Patent No. 6494854 to Visness, and U.S. Patent No. 4452252 to Sackner.

In response to the Examiner's above-referenced rejections, Applicant submits amended claims and addresses the Examiner's concerns herein below.

The New Claims Are Not Anticipated by Wirtz

The Examiner has rejected claims 1-5 and 10-11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4657003 to Wirtz. The Examiner alleges that Wirtz generally discloses a support member having an inner surface, an outer surface, and a peripheral edge; a securing means enabling retention of the support member on the neck; a retention means enabling retention of the securing means relative to the support member; a sealing means that enables airtight positioning of the support member against the neck; an air compartment between the inner surface of the support member and the neck; and a valve that enables air to exit from the air compartment between the inner surface of the support member and the neck.

More specifically, the Examiner argues that Wirtz provides a device for the neck which is fully capable of maintaining air pathway clearance when the alleged air

compartment defined between the support member 82 and the neck is evacuated by the valve 25. Office Action, page 4, para. 7. The Examiner further alleges that Wirtz discloses a sealing means 94 that enables an airtight positioning of the support member 84 against the neck, wherein the sealing means defines an air compartment between the inner surface of the support member and the neck. Still further, the Examiner argues that Wirtz describes a valve 25 that enables the exit of air from the air compartment between the inner surface of the support member and the neck.

Applicant respectfully disagrees with the Examiner's assessment of the alleged sealing means and air compartment as disclosed by Wirtz for the reasons set forth below. Applicant further disagrees with the Examiner's assessment of the valve and its functioning as disclosed in Wirtz.

Wirtz

Wirtz discloses a brace for immobilizing the neck that includes an airtight envelope or bag 82, deformable plastic beads 12 disposed within the bag, a sheet of cushioning material 94 (i.e., soft plastic foam) secured to the inner surface 16 of the bag, and a valve 25 in communication with the interior of the bag for evacuating the same. Wirtz, Figs. 3-5 and 14. In operation and upon placement of the device on the neck, evacuation of air from the interior of the bag via the valve collapses the bag and compacts the beads contained therein. Wirtz, column 3, lines 4-9. The compacting of the beads causes the bag to form a rigid structure to support the neck. Stated differently, the resulting vacuum formed in the bag deforms the beads into a rigid construction to support and restrain the neck. Briefly, Wirtz discloses a flexible neck brace that is rigidified by evacuation. Wirtz, column 9, lines 17-20.

The present invention provides a support member 10; one or more straps 30a, 30b for securing the support member about the neck; strap fasteners 34a, 34b for securing the straps relative to the support member; a seal 38 secured to a peripheral edge 29 of the

inner surface 28 of the support member; an air compartment defined by the inner surface of the support member, the seal, and the neck; and a valve 44 that enables air to exit the air compartment during expansion of the neck. See Figs. 1 and 2.

The Examiner alleges that Wirtz discloses an air compartment defined between the support member 84 and the neck. Office Action, page 4, para. 7. Applicant submits that the only air compartment disclosed by Wirtz is defined by the opposing interior surfaces of the front and back sheets 16 and 18 that form the walls of the bag 10, not the inner surface of the support member and the neck as claimed in the present invention. Wirtz, column 5, lines 1-7, and Fig. 3.

As a depicted in Figures 3 and 14, the inner sheet or wall 16 of Wirtz is substantially planar and includes tapered edges (see Fig. 10) that do not extend beyond or protrude laterally from the inner surface of the bag 10. The lack of laterally protruding edges precludes the formation of a compartment defined by any exterior surface of the bag. Upon filling the interior—and sole—compartment of the bag with air and placing it on, for example, a neck, soft plastic foam or cushioning material 94 material carried by the entire inner surface of the bag extends against and conforms to the neck, thereby preventing contact between the bag's peripheral edges and the neck. Wirtz, column 9, lines 25-27, and Figure 14. Upon the evacuation of air from the interior compartment of the bag, the cushioning material expands and continues to conform to the neck of the user. Accordingly, Wirtz fails to disclose an air compartment defined between the inner surface 16 of the brace and the neck. Instead, Wirtz discloses an air compartment that is defined by the opposing interior surfaces of the front and back sheets 16 and 18 that form the walls of the bag.

In contrast, the support member of the present invention includes a peripheral edge that extends laterally beyond the inner surface of the support member. Cushioning material is secured to and extends substantially coextensive with the peripheral edge of the inner surface of the support member. The cushioning material and protruding

peripheral edge forms a seal that likewise protrudes beyond the inner surface of the support member such that portions of the inner surface of the support member and the neck are spaced apart from one another. Upon placement of the brace on the user, the inner surface of the support member, the peripheral seal, and the neck forms an air compartment that can be evacuated with the valve upon exhalation by the user. In other words, the present invention defines and claims an air compartment defined by an external surface of the support member, the peripheral seal, and the neck, whereas Wirtz discloses an air compartment defined by enclosed interior surfaces of the inflatable bag.

As noted above, the Examiner also alleges that Wirtz discloses a sealing means that enables an airtight positioning of the support member against the neck. Applicant submits that Wirtz fails to disclose a sealing means that is capable of positioning the support member against the neck of the user in an airtight fashion. More accurately—as disclosed in Wirtz and discussed above—the alleged "sealing means" is actually soft plastic foam. Wirtz, column 9, lines 25-27, and Figure 14.

Specifically, the alleged "seal" of Wirtz that is positioned on the entire substantially planar interior of the bag is not capable of forming an airtight compartment between the support member and the neck. Upon placement of the Wirtz bag on the neck, the plastic foam covering the entire interior surface of the brace "engage[s] the skin of the wearer." Wirtz, column 9, lines 25. Upon evacuation of the interior of the bag, the sheet of soft plastic foam taught by Wirtz expands and conforms to the disposition of the beads and surface of the neck. In other words, the foam expands upon evacuation of the bag as secured to the neck and fails to form any discernible "air compartment" as alleged by the Examiner. The rigid nature of the evacuated support member, in conjunction with its tapered edges and foam material secured thereto, fails to provide a surface capable of forming a seal between the interior surface of the brace 16 and the neck.

In contrast, the present invention provides a seal 38 that is capable of forming an airtight positioning of the support member 20 against the neck. Specifically, the seal is

defined by the peripheral edge of the support member that extends laterally from the surface of the support member. More specifically, the seal is secured to and extends substantially coextensive with the peripheral edge of the inner surface of the support member. Further, the seal formed on the peripheral edge of the support member protrudes beyond (i.e., extends laterally from) the inner surface of the support member such that portions of the inner surface of the support member and the neck are spaced apart from one another. Upon placement of the brace on the user, the inner surface of the support member, the peripheral seal, and the neck forms an air compartment that can be evacuated with the valve upon exhalation by the user.

As referenced previously, the Examiner further argues that Wirtz describes a valve that enables the exit of air from an air compartment between the inner surface of the bag and the neck. Applicant submits that the valve taught by Wirtz enables exit of the air from the interior of the bag and does not promote the evacuation of air from between the bag and the neck of the user. Specifically, evacuation of air from the bag merely permits the cushioning material to expand against the user's neck.

Again, the only air compartment capable of evacuation by a valve as disclosed in Wirtz is the air compartment defined by the interior surfaces of the sheets that define the bag. The valve disclosed by Wirtz is positioned on the bag and is in communication with the bag interior. This arrangement permits evacuation of the interior of the bag by a manually activated or power driven pump. Wirtz, column 3, lines 65-67. The valve of Wirtz is not capable of evacuating air from between the inner surface of the support member and the neck because that area is filled with cushioning material and is not sealed as a result of the tapered edges.

In contrast, the valve of the present invention enables air to exit from the air compartment defined by the support member, seal, and neck following the expansion of the soft tissues of the neck during exhalation. During subsequent inhalation, negative

pressure is created in the air compartment such that the negative pressure on the exterior service of the neck effectively draws open the air passages of the user.

Accordingly, Wirtz does not teach or suggest a support member having an air compartment defined by the inner surface of the support member and the neck that is capable of evacuation by a valve, nor does Wirtz teach a sealing means that enables air tight positioning of the support member against the neck. To the contrary, Wirtz teaches away from the sealed air compartment between the inner surface of the support member and neck by disclosing a brace having tapered edges and cushioning material covering the entire planar surface of the brace interior such that the cushioning material and tapered edges prevent the formation of a seal. Thus, Wirtz does not disclose all of the elements described in claims 1-5 and 10-11 of the invention and therefore must be removed as a §102 (b) reference.

The Claims are not Obvious in View of Prior Art

The Examiner rejects claims 6-9 and 12-20 under 35 U.S.C. §103(a) as being unpatentable over Wirtz in view of—either alone or in combination with—U.S. Patent No. 4886052 to Calabrese, U.S. Patent No. 6494854 to Visness et al., and U.S. Patent No. 4657003 to Sackner.

The Cited References

The Examiner alleges that Wirtz discloses all limitations recited in claims 6-9, and 16, and discussed above, but does not expressly disclose a securing means that includes both a strap and another attachment mechanism, and does not expressly disclose that the support member is formed of a plurality of linked segments. The Examiner argues that Calabrese discloses a variety of suitable fastening means and attachment mechanisms as claimed in the present invention.

The Examiner alleges that Wirtz discloses all limitations recited in claims 12, 17-18 and 20, and discussed above, with the exception of a gasket. The Examiner argues that Visness teaches the use of a gasket to disperse and cushion the weight of the device, and to define a sealed region between the surface of the neck cuff and the neck.

The Examiner alleges that Wirtz discloses all limitations recited in claims 13-15, and 19, and discussed above, with the exception of a data collection port and means for measuring performance. The Examiners argues that Visness and Sackner in combination teach the use of a device with a data collection port and a means for analyzing various pulmonary events.

Applicant respectfully disagrees with the Examiner's assessment of the air compartment and seal as disclosed by Wirtz, the fastening means as disclosed by Calabrese, the gasket as disclosed by Visness, and the data collection port and means for measuring performance as disclosed by Sackner in combination with Visness.

Wirtz

The alleged "air compartment" between the inner surface 16 of the bag 10 and the neck as disclosed in Wirtz is in fact an area filled with cushioning material 94 that conforms to and rests against the entire surface of user's neck; thus, Wirtz fails to disclose an "air compartment." The only air compartment disclosed by Wirtz is defined by the interior of the bag. In brief, Wirtz teaches a substantially flat bag that rigidifies upon evacuation of air from the interior of the bag. Further, the tapered nature of the edges of the Wirtz brace prevents the formation of a seal. See Fig. 10. Thus, Wirtz teaches the use of an air compartment defined by the opposing interior surfaces of the sheets 16, 18 forming the bag, and tapered edges that permit the cushioning material 94 to rest against the neck—such that the cushioning material is sandwiched between the inner sheet 16 and the neck. Accordingly, Wirtz, taken either individually or in combination with Calabrese, does not teach or suggest an air compartment defined by the

inner surface of the neck brace, protruding edges at the periphery of the brace, and the neck of the user.

Further, the alleged "seal" of Wirtz is incapable of facilitating airtight positioning of the brace on the neck. Specifically, the Examiner has identified the cushioning material as a seal. In this case, cushioning material secured coextensively to the entire surface of a substantially flat structure (i.e., the bag forming the brace of Wirtz) having tapered edges is not capable of forming a seal. Absent a protruding rim or edge—as provided in the present invention—the inner surface of Wirtz cannot create a seal upon evacuation of the interior of the bag.

Stated differently, Wirtz fails to teach the use of a seal secured to protruding peripheral edges of the support member such that the interior of the support member and neck are spaced apart. To the contrary, Wirtz teaches away from an air compartment between the inner surface of the support member and the neck, and a seal for maintaining negative pressure therein, by disclosing an air compartment formed within the integral structure of the bag and defined by the enclosed interior surfaces of the sheets forming the bag, wherein tapered edges provided on the bag are flush with the bag surface.

Calabrese

Calabrese describes a cervical collar for immobilizing the cervical portion of a victim's spine. Although Calabrese teaches the use of a number of fasteners to secure the collar about the neck (or segments thereof), there is no motivation to combine Calabrese with Wirtz to arrive at the present structure because Wirtz fails to teach the use of a seal formed by protruding peripheral edges of a brace to thereby facilitate the formation of an air compartment between the inner surface of the support member and the neck. The combination of Wirtz and Calabrese results in a cervical immobilizer that includes an inner surface having cushioning material positioned flush against the neck upon evacuation of an air compartment formed between the interior sheet surfaces of the brace,

wherein a variety of fasteners secure the brace about the neck. This combination is incapable of forming a seal between a surface of the brace and the neck, and fails to suggest the creation of negative pressure against the user's neck to maintain air pathway clearance.

Accordingly, Wirtz, taken either individually or in combination with Calabrese, does not teach or suggest an air compartment between portions of the brace and the neck or a seal formed about the periphery edge of the brace. Further, Wirtz, taken either individually or in combination with Calabrese, fails to even suggest a modification to arrive at the subject air compartment or seal. Still further, the incorporation of Calabrese's fasteners into the bag of Wirtz fails to render elements of the present invention obvious because Wirtz does not suggest a support member of type claimed in the present application.

Visness

Visness discloses a cervical collar for immobilizing the head and neck of the patient. The Examiner argues that the gasket member 100 defines a sealed region between the concave surface of the neck cuff (or support member) and the neck of the user. Applicant submits that while a gasket may form a seal when applied to, for example, a surface having protruding edges that form part of an enclosure, the use of the gasket in combination with the structure of Wirtz fails to render the present invention obvious.

As known to those skilled in the art, a seal serves to form a closure or to prevent the passage of a medium (e.g., air or water). Accordingly, a seal provides closure to some sort of defined enclosure such as an air compartment. In this case, the gasket of Visness as applied to the structure of Wirtz fails to prevent the passage of air—or any medium for that matter—because Wirtz as applied to the neck fails to define an air compartment between the inner surface of the brace and the neck of the user. Stated

differently, the Visness gasket as applied to the brace of Wirtz fails to result in a seal formed at the peripheral edges of the brace. Rather, the combination of Wirtz and Visness results in a neck brace having cushioning material secured to the entire inner surface 16 (as in Wirtz) and along the bottom edge 31 (as in Visness) of a brace that distributes weight across the chest of the user. Upon evacuation of the air from the interior of Wirtz, the bag becomes rigid, and the cushioning material of Wirtz as disposed on the entire inner surface of the bag and the "gasket" of Visness as secured to the bottom of the bag conforms to the neck surface, such that the cushioning material and gasket are immediately adjacent to the inner surface of the brace and the neck of the user—thereby precluding the formation of an air compartment or a seal.

Accordingly, Wirtz, taken either individually or in combination with Visness, does not teach or suggest a seal provided on the periphery of the brace edges, nor does the combination teach or suggest an air compartment defined by the interior surface of the brace, protruding edges at the periphery of the brace, and the neck of the user.

Sackner

Sackner discloses a method for monitoring cardiopulmonary events comprising the steps of placing a detector about the neck, providing a signal capable of detection by the detector, and monitoring the signal which is indicative of cardiopulmonary events. Applicant submits that the modification of Wirtz to include a data collection port and a device for monitoring vital signs fails to render the present invention obvious.

As indicated above, Wirtz fails to disclose an air compartment between the inner surface of the support member and the neck of the user, and also fails to describe a seal that promotes airtight positioning of the brace on the neck. Accordingly, the incorporation of the data collection port of Sackner into the bag of Wirtz would result in a neck brace lacking the subject air compartment and seal, but capable of collecting data. In contrast, the subject invention provides a neck brace having an air compartment

between the inner surface of the support member and the neck of the user, a seal capable of promoting a negative pressure in the air compartment, and a data collection port for use in connection with a monitoring device.

Applicant submits again that Wirtz fails to stand as proper prior art, and any combination with Sackner does not teach or suggest a neck brace having an air compartment (between the inner surface of the brace and the neck of the user) that relies upon a seal formed about the peripheral edge of the brace, to thereby maintain negative pressure in the air compartment and maintain the air pathways of a user open.

In view of the structural distinctions between the present invention and the cited references, Applicant submits that combining Wirtz—either alone or in combination with—Calabrese, Visness, or Sackner in a way that renders the present invention obvious relies on impermissible hindsight.

Amended Independent Claims 1 and 17 are Patentable

Amended independent claims 1 and 17 define an air pathway clearance device for wear on the neck that is not anticipated, nor rendered obvious, by the references cited by the Examiner. The amended independent claims 1 and 17 define a seal secured to and extending coextensively with the peripheral edge of the inner surface of the support member, wherein the peripheral edge extends beyond the inner surface of the support member such that the inner surface is spaced apart from the neck of the user (i.e., defining a compartment). As configured, and defined in the amended claims, the protruding peripheral edge facilitates the formation of an air compartment defined by an area bound by the inner surface of the support member, the seal, and the neck of the user. The amended independent claims further define a device that permits the creation of negative pressure in the air compartment during inhalation such that the negative pressure on the exterior surface of the neck holds open air pathways of the user.

In contrast, Wirtz fails to describe, teach, or suggest a device for maintaining clearance of an air pathway that includes an air compartment defined by an inner surface of the support member, a seal extending along the protruding periphery edges of the support member, and the neck of the user, such that exhalation and subsequent inhalation by the user creates a negative pressure in the air compartment, wherein the negative pressure on the exterior surface of the neck holds open the air pathways of the user. Further, Wirtz—alone or in combination with—Calabrese, Visness, or Sackner, fails to disclose, teach, or suggest a device that includes an air compartment that is secured with a seal extending coextensive with the protruding periphery edge of the support member, to thereby enable airtight positioning of the device on the neck. Accordingly, Applicant submits that the amended claims include patentable subject matter and are now allowable.

Amended Dependent Claims now Conform to the Amended Independent Claims

Applicant has amended dependent claim 5 to include the letter "a" between the words "is" and "hook" such that the claim now recites that the retention means "is a hook and loop fastener"—as opposed to "is hook and loop fastener." Further, Applicant has amended dependent claim 8 to reflect that the retention means is "at least one clasp"—as opposed to "at least clasp." Applicant has also amended dependent claim 12 to conform to amended independent claim 1, namely reciting that the "sealing means" is a "seal."

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CONCLUSION

Based on foregoing amendments and arguments, Applicant submits that pending Claims 1-20 are now in immediate condition for allowance, and the same is respectfully requested. Presently, the fee for the total number of all claims (i.e., 20) pending in this application is less than or the same as the total number of claims (i.e., 24) that Applicant paid for at filing. Thus, Applicant believes that no additional fees are due. Nevertheless, the Commissioner is authorized to charge any additional fee, or credit any refund, to our Deposit Account No. 50-0332.

Respectfully submitted,

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Patricia Summers